

Variation in measurement of ankle-brachial pressure index in routine clinical practice

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Purpose: The purpose of this study was to determine the variation in ankle-brachial pressure index (ABPI) measurements in routine clinical practice.

Methods: Analysis was done of preoperative and postoperative ABPIs in 130 limbs contralateral to those undergoing femoral bypass grafting in 123 patients over a 15-month period.

Results: The mean initial ABPI was 0.72 (range 0.22 to 1.10). The range of observed differences between the preoperative and postoperative ABPIs was from -0.33 to $+0.25$. The mean (\pm SD) difference between the first and second ABPIs was $0.00 (\pm 0.11)$. The 95% confidence limits of the difference were -0.21 to 0.21 . There was no trend for the size or direction of the difference in ABPI to vary according to the mean ABPI, brachial blood pressure, or time between tests.

Conclusions: ABPI is routinely used as an objective measure of peripheral vascular disease. The variation observed in this study is comparable with values obtained in reproducibility studies and is greater than that accepted in clinical practice. The difference between an ABPI measurement and the actual ABPI and the difference between repeat single measurements are not the same and should be distinguished. Vascular laboratories should determine the accuracy of ABPI measurement on a local basis to guarantee and maintain quality assurance. (*J Vasc Surg* 1996;24:871-5.)

In current vascular surgical practice the ankle-brachial pressure index (ABPI) is widely used as an objective measure of the severity of limb arterial ischemia, the progression of disease, and the results of intervention. An accuracy of measurement of ABPI of ± 0.15 is widely accepted, and variation greater than this is considered "significant." The aim of this study was to determine the variation in ABPI in routine clinical practice.

MATERIAL AND METHODS

Patient population and exclusions. Data on 190 consecutive patients undergoing 214 femoral bypass procedures on 206 limbs at Royal Prince Alfred Hospital Department of Vascular Surgery over a 15-month period were reviewed. Eighty-four opera-

tions in 76 limbs in 64 patients were excluded because of initial indeterminate ABPI (>1.20), previous contralateral amputation, repeat operations, one or other ABPI not being performed by our vascular laboratory, or bilateral procedures undertaken between tests (Table I).

ABPI measurements. All ABPI measurements in this study were made in routine clinical practice in the vascular laboratory at Royal Prince Alfred Hospital Department of Vascular Surgery or Camperdown Vascular Laboratory as part of the preoperative and postoperative assessment of patients by one of four certified (Diploma of Medical Ultrasound Australasian Society for Ultrasound in Medicine) and RVT (USA) technologists, each with more than 10 years of clinical experience in vascular technology. The technologists were not aware that these observations would be used for an analysis of reproducibility and were not necessarily blinded to previous ABPI measurements.

Method of measurement. ABPI assessments were carried out with a standard method with one of two identical sets of equipment. The patient was positioned supine for 10 minutes before testing was begun, with clothing over the lower limbs removed in

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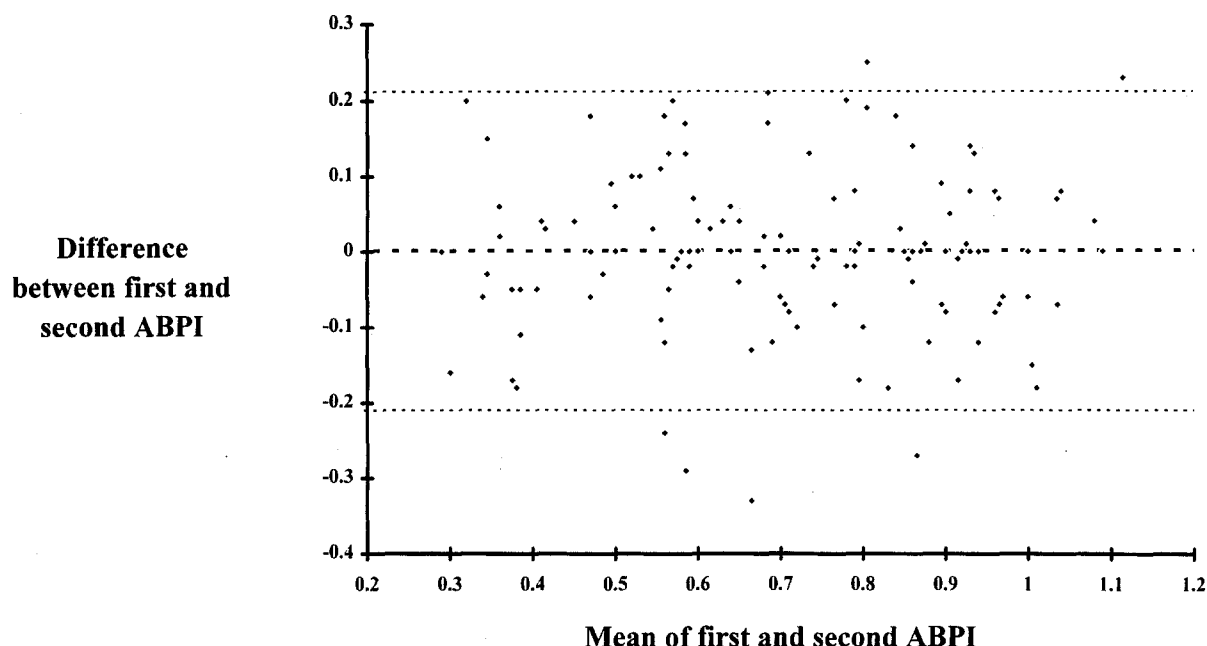


Fig. 1. Mean of first and second ABPI measurements ($n = 130$) plotted against difference between each of individual ABPI results (*), mean difference between first and second ABPI (---), and 95% confidence limits of difference between first and second ABPI (.....).

Table I. Frequency distribution of inclusions and exclusions

	Operations	Limbs	Subjects
Included	130	130	123
Excluded			
Previous amputation	6	4	4
Bilateral procedures	21	21	14
Repeat operation	21	17	17
Indeterminate ABPI	13	11	11
ABPI not done	23	21	21
Total	214	206	190

an air-conditioned room with a usual temperature of 22° C to 23° C. The brachial systolic blood pressure was determined in both cubital fossae with a 5 MHz handheld ultrasound probe and a Hokanson (D Hokanson Co, Issaquah, Wash.) pneumatic tourniquet. With the same equipment ankle systolic blood pressures were then determined in the dorsalis pedis and posterior tibial arteries. The number of measurements required for each formal determination of ABPI was at the discretion of the individual vascular technologist. The ABPI for each limb was calculated as the higher of the two pedal artery systolic pressures divided by the higher brachial artery systolic blood pressure.

The most recent ABPI before surgery and the first ABPI after surgery performed by the vascular labora-

tory were evaluated. Measurements of ABPI performed by medical staff in the vascular clinic, office, or immediate postoperative period were not included.

Statistical methods. The mean difference and the 95% confidence limits (95% CL) of the difference between the first and second ABPI were calculated and plotted according to the methods of Bland and Altman¹ for the determination of the repeatability of observations.

RESULTS

Of the 123 patients evaluated, 64 (49%) were male. The mean age (\pm SD) was 70 (\pm 9) years. No significant difference in age was present between men and women. The minimum initial ABPI was 0.22, and the maximum initial ABPI was 1.10. The mean (\pm SD) initial ABPI was 0.72 (\pm 0.21). The median (interquartile range) initial ABPI was 0.73 (0.52 to 0.92).

The median (interquartile range) time between initial ABPI measurement and surgery was 44 (5 to 97) days, surgery and postoperative assessment 4 (4 to 5) days, and overall time between tests 51 (10 to 103) days.

The range of change in observed ABPIs after surgery was from -0.33 to +0.25. In three limbs decreases in ABPI (-0.33, -0.29, and -0.27) were greater than the maximum individual increase (+0.25). No significant clinical deterioration occurred

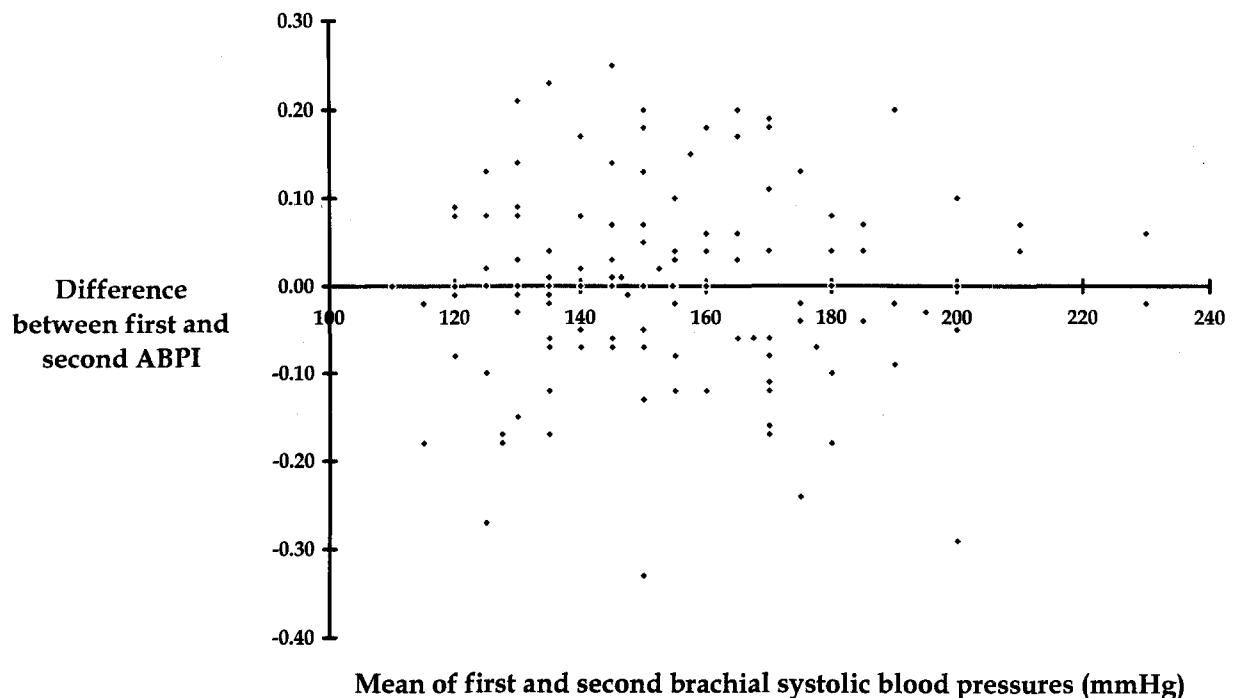


Fig. 2. Mean of first and second systolic maximum brachial blood pressure measurements ($n = 130$) plotted against difference between each of individual ABPI results (*).

in these limbs, and in the next 3 months no intervention for ischemia was required in any of these three limbs. In the remaining 127 limbs the maximum observed fall (-0.24) in ABPI was less than the maximum observed individual rise ($+0.25$).

The mean (\pm SEM) difference between the first and second ABPI was $0.00 (\pm 0.01)$ with 95% CL of the mean of -0.02 to $+0.02$; that is, no net change occurred in the ABPI between tests. The standard deviation of the difference between the first and second ABPI was 0.11 with 95% CL of the difference, which is the amount by which measurements must differ before a difference can be recognized at the 95% CL, of ± 0.21 (Fig. 1). The size and direction of the difference in ABPI did not vary with mean ABPI, mean brachial blood pressure (Fig. 2, $r^2 = 0.02$), or interval between tests ($r^2 = 0.01$).

Exclusion of the three patients with observed falls in ABPI changed the observed differences only slightly to a mean difference (\pm SD) of $0.01 (\pm 0.10)$ with 95% CL for the difference of -0.19 to 0.21 .

DISCUSSION

Measurement of leg blood pressures in peripheral arterial disease with noninvasive methods was performed more than 40 years ago by Winsor² and later by Yao et al.³ with Doppler ultrasonography. The

ABPI is now a standard noninvasive investigation in peripheral vascular occlusive disease and is a good predictor of survival in patients with claudication.⁴ A change in ABPI greater than 0.15 is widely accepted in current vascular practice as "significant," providing, for example, objective evidence of hemodynamic improvement after intervention or confirmation of clinical deterioration. An increase of only 0.10 in ABPI is currently recommended as part of the objective criteria of successful intervention.⁵

The variation in ABPI in this study was ± 0.21 . Three patients had an observed fall in ABPI greater than -0.25 . It is possible that these patients in particular may have undergone a *real* deterioration in arterial perfusion rather than variation in the observed ABPI. Possible mechanisms for this deterioration include arterial thrombosis caused by direct vessel trauma from arteriography, perioperative hypotension, or hypercoagulability.

It can be safely hypothesized that there was no real difference between each pair of ABPIs in the remaining 127 limbs and most probably in all 130 limbs assessed. That is, the actual ABPI did not change significantly, and any difference observed has arisen solely as a result of variations in measurement.

Practitioners should also distinguish between the 95% CL of the difference between repeat individual

Table II. Difference between individual ABPI and mean (actual) ABPI

<i>Author</i>	<i>Reference</i>	<i>Observers</i>	<i>Observations/patient</i>	<i>Mean ABPI (overall)</i>	<i>Reported results</i>	<i>95% CL*</i>	<i>Comments</i>
Magee et al.	6	4	4	Not stated	In 58 of 66 limbs, all 4 observers found ABPI within ± 0.15 of each other	± 0.09	
Johnston et al.	7	Multiple	Multiple	0.64	95% CL ± 0.10	± 0.10	15 Patients
Fowkes et al.	8	Multiple	8	0.72	95% CL ± 0.11	± 0.11	24 Subjects
Ouriel et al.	9	Not stated	10	Not stated	Relative SD 9.5%	± 0.12	Mean ABPI of all claudicants and not reproducibility subgroup
Baker and Dix	10	Single	6.8	0.62	SD of observed difference 0.072	± 0.15	Individual measurement accepted only after two readings obtained ± 5 mm Hg
Stoffers et al.	11	59	Multiple	0.81	95% CL ± 0.22	± 0.22	9 Subjects (3 normal)

*Where 95% CL was not stated, 95% CL was calculated from reported results with standard methods.

Table III. Difference between two individual ABPI measurements

<i>Author</i>	<i>Reference</i>	<i>Observers</i>	<i>Mean ABPI</i>	<i>Reported results</i>	<i>95% CL*</i>	<i>Comments</i>
Fowkes et al.	8	Multiple	0.72	95% CL ± 0.11	± 0.11	24 Subjects
Johnston et al.	7	Multiple	0.64	95% CL ± 0.16	± 0.16	
Osmunden et al.	12	Not stated	0.80	80% Values lay between -0.11 to $+0.10$ of mean difference	± 0.16	
Fisher et al.	(current)	Multiple	0.72	95% CL ± 0.21	± 0.21	
Stoffers et al.	11	Multiple	0.81	95% CL ± 0.24 -0.29	± 0.24	If two observations are used for each measurement (9 subjects, 3 nonclaudicant)
Clyne et al.	13	Not stated	0.50	CV 24%	± 0.24	Worse limb studied. Preexercise results for better limb not stated. Postexercise 95% CL for better limb ± 0.22 .

*Where 95% CL was not stated, 95% CL was calculated from reported.

measurements of ABPI and the 95% CL of the difference between a single ABPI and the actual ABPI, estimated as the mean of multiple measurements of the ABPI. The former measurement is the amount a repeat ABPI needs to differ from the initial ABPI measurement before a significant difference can be detected at the 95% CL. The latter measurement is the amount a single ABPI measurement must differ from the mean ABPI before a difference in the ABPI can be recognized at the 95% CL and is less than the former measurement. It should be remembered that the calculated mean ABPI is itself only an estimate of the true ABPI and has its own standard error, which is reduced by a greater number of observations.

The 95% CL of the variability of ABPI with

Doppler evaluation in formally conducted reproducibility trials has been calculated with the published data and is listed in Tables II and III according to which of the previous differences has been assessed. In particular, Baker and Dix¹⁰ determined that a difference of ± 0.15 between the observed ABPI and the mean ABPI was required for a significant difference to be recognized at the 95% CL. This figure is frequently quoted, but in clinical practice the reference ABPI usually used is a single estimate, either because the ABPI has only been determined at one previous examination or only the results of the last examination have been used.

Therefore a repeat ABPI performed to assess the results of intervention or progression of disease

should be compared with a mean ABPI determined from multiple measurements where available, as Baker and Dix recommended, making a smaller change in ABPI able to be recognized as significant. If the possible variation in ABPI is not recognized and appreciated, then the reliability of assessment of the success of intervention or progression of disease will be diminished.

The observed variation in ABPI arises as a result of variation in the patient and in the method of measurement (intraobserver and interobserver variation). The results of this study with values observed in routine clinical practice are comparable to those determined in formally conducted studies. However, these studies may not necessarily reflect routine clinical practice, and in particular vascular laboratory staff performance could be altered by knowledge of participation in a formal reproducibility study.

Several studies have used single observers to eliminate differences arising as a result of different observers. All ABPIs in this study were performed by certified and experienced vascular laboratory technologists to avoid errors that are thought to arise from inexperience or poor technique.¹³

Furthermore the vascular technologists were not blinded to the previous ABPI result nor to the history of the recent procedure on the contralateral limb. It would be expected that if knowledge of the previous result resulted in bias in measurement of the ABPI, this bias subsequently would be differential and would tend to *reduce* rather than increase the size of the difference. When interobserver, intraobserver, and biologic variations in patients have been specifically assessed, within-patient variation has been responsible for most of the observed variation.⁹

In this study the observed variation of ± 0.21 for repeat ABPI measurements from the initial single ABPI measurement is comparable with those of other published studies.^{7,8,11-13} This variation is greater than the widely accepted value of ± 0.15 , applicable only to the difference between the observed and the actual ABPI. Practitioners and vascular laboratories should take care to distinguish between these two values when reporting results and should determine and monitor the variations in measurement in their own

facilities. The size of the difference in repeat ABPIs required to demonstrate significant change should be broadened to 0.21 when the ABPI has not been determined from multiple observations.

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